Remarks

Claims 1-28 and 36-46 were pending in the subject application. By this Amendment, claims 15-28 and 36-46 have been cancelled and new claims 47-50 have been added. Support for the new claims can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-14 and 47-50 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Claims 1-14 are rejected under 35 USC §112, second paragraph, as indefinite. Specifically, the Examiner asserts that the term "immune response" is vague and indefinite. The Examiner asserts that the type of immune response is not clear, nor is the purpose that the immune response serves. In addition, the Examiner asserts that the claims are incomplete for omitting essential steps. Applicants respectfully traverse this ground of rejection.

Applicants respectfully assert that the claims are clear and definite. As to the type of immune response, Applicants respectfully assert that the independent claims contemplate any type of immune response; thus, there is no need to specify the type. The purpose of the claimed method is self evident: to generate an immune response (of any type) against FIV in a human or non-feline animal or against HIV in a human. Thus, Applicants respectfully assert that the claims are clear and definite as to the immune response.

Presumably in regard to claims 1-7, the Examiner asserts that FIV is a lentivirus specific for felines and does not infect non-feline hosts. Applicants respectfully assert that FIV is capable of infecting non-feline animals. Applicants have addressed this issue in the response to the rejections under 35 USC §101 and 35 USC §112, first paragraph. Applicants' comments in regard to those rejections are hereby incorporated in regard to this rejection.

Applicants also respectfully assert that the claimed method does not omit any essential steps. The essential step is to administer an effective amount of an FIV immunogen to the subject to induce an immune response to FIV (for claims 1-7) or to HIV (for claims 8-14). Applicants respectfully assert that step is the only essential step in the claimed method in that the immune response is thereby generated.

In view of the above remarks, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 1-14 are rejected under 35 USC §101 and §112, first paragraph, on the grounds the claimed invention is not supported by a well-established utility. The Examiner appears to be of the opinion that FIV cannot infect animals other than felines and, therefore, there is no use for the claimed invention. Applicants note that the comments concerning lack of utility of the invention are in regard to the inability of FIV to infect non-feline animals. These comments do not appear to be relevant to claims 8-14, which are not concerned with FIV infection of a non-human animal. Thus, Applicants will assume that claims 8-14 are not included under these rejections. Applicants respectfully traverse these grounds of rejection.

Applicants respectfully assert that the subject application does teach a sufficient utility for the claimed invention. Specifically, the utility for the claimed invention is the prevention and/or treatment of FIV infection in a human or non-feline subject. Applicants respectfully assert that, in contrast to the Examiner's definition, infection by a virus does not necessarily cause a disease in the host. The subject specification teaches, in contrast to the Examiner's assertions, that humans can be infected by FIV. In particular, the subject specification teaches the infection of human subject #FH1 by FIV at page 19, line 4 through to page 20, line 4. This subject exhibited antibody reactivity to FIV proteins, such as p24 (see Figure 1). Sera from subject #FH1 was able to neutralize FIV but not HIV-1, *in vitro*. More importantly, the subject specification discloses that subject #FH1 was positive for the presence of FIV *gag* gene in the subject's peripheral blood mononuclear cells (see page 19, lines 13-23, and Example 3 of the subject specification). This evidence is indicative of FIV infection of the human subject. Another human subject, #FH2, was also found to be infected with FIV, as indicated in the subject specification at page 21, lines 8-26 ("This observation together with our Gag/*gag* sequence results suggests that this subject is actively or defectively infected with FIV.").

Applicants further note that the Poeschla and Looney (1998) and Butera *et al.* (2000) references cited by the Examiner do not represent the state of the art with regard to FIV infection. Applicants have cited in the Information Disclosure Statement dated July 24, 2003 a reference by Johnston *et al.*, *Current Biology* (2001) 11:1109-1113 (which was published after Applicants' earliest effective filing date) which shows that "macaques infected with FIV exhibited clinical signs,

including depletion of CD4+ cells and weight loss, that are consistent with FIV infection." This is consistent with Applicants' disclosure that FIV can infect non-feline animals.

In view of the results provided in the subject specification showing that a non-feline animal can be infected with FIV, and in view of the fact that FIV is known to cause a disease condition in infected cats, there is a clear, sufficient utility for preventing and/or treating FIV infection in non-feline animals. Thus, Applicants respectfully assert that the utility requirement of 35 USC §101 and §112, first paragraph, is satisfied. Reconsideration and withdrawal of the rejections under 35 USC §101 and §112, first paragraph, is respectfully requested.

Claims 1-14 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. The Examiner asserts that the subject specification does not teach a person of ordinary skill in the art "how to use" the claimed invention. This rejection is related to the §101 utility rejection in that the Examiner asserts that there cannot be a use for inducing an immune response against FIV in a non-feline animal if one accepts that only felines can be infected with FIV. The Examiner asserts that FIV does not establish a viral infection in non-feline animals and therefore states that "induction of an immune response for therapeutic or prophylactic purposes seems unlikely." Applicants note that the comments concerning lack of enablement of the invention are in regard to the inability of FIV to infect non-feline animals. These comments do not appear to be relevant to claims 8-14, which are not concerned with FIV infection of a non-human animal. Thus, Applicants will assume that claims 8-14 are not included under these rejections. Applicants respectfully traverse this ground of rejection.

Applicants respectfully assert that the subject specification teaches the ordinarily skilled artisan "how to use" the claimed invention. To the extent under this rejection that the Examiner is of the opinion that there is no use for inducing an immune response against FIV in a non-feline animal, Applicants respectfully incorporate herein their remarks submitted in regard to the rejection under 35 USC §101 and 35 USC §112 for lack of utility. Applicants have discussed that the results in the subject specification show that non-feline animals, such as human, can be infected by FIV. Thus, Applicants respectfully assert that the induction of an immune response for therapeutic or prophylactic purposes in non-feline animals is valid and, therefore, the subject specification does teach "how to use" the claimed invention.

In regard to the Examiner's comments regarding the lack of working embodiments wherein an FIV immunogen is administered to a non-feline animal to induce a protective or therapeutic immune response against FIV, Applicants first note that 35 USC §112, first paragraph, does not mandate that an applicant for patent disclose working embodiments. All that is required is that the specification teach a person of ordinary skill in the art how to make and how to use the claimed invention. Applicants maintain that the subject application teaches infection of non-feline animals by FIV. It is well known in the art that FIV infection in cats can be prevented or treated by immunizing with FIV immunogens (see, for example, U.S. Patent Nos. 6,254,872; 5,846,825; 7,267,824; 6,544,528; 6,447,993, 6,605,282; and 7,311,921). Thus, a person of ordinary skill in the art would reasonably expect that FIV infection of a non-feline animal could be treated or prevented by administering an FIV immunogen to induce an immune response to FIV in the non-feline animal.

Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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Attachment: Petition and Fee for Extension of Time